



Ghana Laboratory Viral Load Testing

EXPANSION PLAN

2017-2020



September 2017



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Foreword

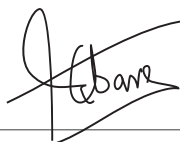
HIV prevalence in Antenatal care clients in 2016 was 2.4% (C.I: 2.18% – 2.62%)¹ and 1.62% (C.I: 1.3% – 2.0%) in the general population. In 2016, there were an estimated 293,804 Persons Living with HIV (PLHIV), nearly 60% of whom are women and 15% are children below 15 years.²

The provision of comprehensive care for Persons Living with HIV using Highly Active Antiretroviral Therapy (HAART) in Ghana over a decade now has impacted greatly on the lives of many. At the end of 2016 there were 245 Antiretroviral Therapy (ART) sites in the ten regions across the country. As at end of December 2016 there were 100,665 clients on ART out of the cumulative number of PLHIV ever enrolled in ART care. With a relatively lower Paediatric ART coverage of ~30%, the total unmet need for ART is approximately 65%.

With emerging new evidence in therapeutic outcomes world-wide and changing trends in the management of PLHIV, Ghana has made a major shift from ART initiation criteria using the World Health Organization (WHO) clinical stage 3&4 and or CD4 count of <500cells/mm to “Treat All” policy in line with 2015 WHO recommendations for the comprehensive care of PLHIVs. Ghana has also adopted the global UNAIDS 90/90/90 aspirational targets in order to sustain the progress being made in the area of care for PLHIV towards ending the AIDS epidemic by 2030.

The recent WHO consolidated guidelines for ART in 2016 reinforced the need for a shift from the use of CD4 testing to the use of Viral Load (VL) testing for the routine monitoring of PLHIVs on ART. Due to the previous policy where viral load testing was mainly to guide decisions on treatment failure, Ghana’s Viral Load coverage was very low and the existing 8 functional VL equipment were grossly underutilized.

Due to the anticipated significant rise in VL testing occasioned by Ghana’s adaptation of 2016 ART guidelines, it has become necessary to develop this VL scale-up and operational plan to assure complete client access to laboratory monitoring towards the achievement of the third 90 of the HIV care cascade. The plan will enhance VL testing, monitoring whilst improving the clinical and laboratory interface for improved client care. This document has been developed for use by all levels of health care facilities; and will assist to provide high quality, effective and standardized VL testing to monitor patients on ART as part of quality health care service delivery in the country.



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¹ 2016 HIV Sentinel Survey Report, National AIDS/STI Control Programme, Ghana Health Service

² 2016 National HIV Prevalence & AIDS Estimates report (SPECTRUM), Ghana AIDS Commission

Glossary

AIDS	Acquired Immunodeficiency Syndrome
APHL	Association of Public Health Laboratories
AR	Ashanti Region
ART	Anti-retroviral therapy
ASLM	African Society for Laboratory Medicine
BAR	Brong Ahafo Region
CR	Central Region
EID	Early Infant Diagnosis
EQA	External Quality Assurance
ER	Eastern Region
GAR	Greater Accra Region
GIS	Geographic Information System
HIV	Human Immunodeficiency Virus
HTS	HIV Testing Services
IQC	Internal Quality Control
M&E	Monitoring and evaluation
MLS	Medical Laboratory Scientist
NACP	National AIDS/STI Control Programme
NR	Northern Region
PCR	Polymerase Chain Reaction
PLHIV	Persons living with HIV
PMTCT	Prevention of mother-to-child transmission
QMS	Quality Management System
SLIPTA	Stepwise Laboratory Quality improvement Towards Accreditation
SLMTA	Strengthening Laboratory Management Toward Accreditation
SOPs	Standard Operating Procedures
STI	Sexually Transmitted Infections
SWOT	Strengths - Weaknesses -Opportunities -Threats
UER	Upper East Region
UWR	Upper West Region
VL	Viral load
VLMS	Viral Load Management System
VR	Volta Region
WHO	World Health Organization
WR	Western Region

a.

INTRODUCTION

Background

The Human Immunodeficiency Virus (HIV) was first identified in Ghana about three decades ago. Since then, there have been many developments in the response to the epidemic. At the end of 2016, the national prevalence of HIV in Ghana was 1.62% and 2.4% among pregnant women; there was an estimated 293,804 persons living with HIV whilst new infections were 20,418 annually³. Also, there were 245 Anti-Retroviral Therapy (ART) and 2,325 Prevention of Mother-To-Child transmission of HIV Testing Sites (PMTCT/HTS) with a total of 100,665 persons living with HIV (PLHIV) on ART⁴.

With new data on therapeutic outcomes world-wide and changing trends in the management of PLHIV, Ghana is moving away from using the ART initiation criteria of WHO clinical stages 3 and 4, and/or CD4 count of ≤ 500 cells/mm³ to offering treatment for all persons with confirmed diagnosis of HIV in accordance with the World Health Organization Recommendations (November 2015). The new recommendations also requires the use of VL testing rather than CD4 count to routinely monitor clients on ART. Ghana adopted these recommendations in the newly revised 2015 Guidelines for ART delivery. Hitherto, VL testing was used to monitor treatment failure and was not a universal basic requirement for monitoring clients on ART in Ghana. Although there may be considerations for VL testing prior to initiation of therapy, it is still not a requirement for initiation of ART. In line with the current WHO recommendations, VL testing is to be conducted in all clients 6 months after initiation of therapy, 12 months after initiation of therapy and, subsequently, at least once yearly thereafter, as a routine way of monitoring clients on ART in order to assess management outcome, disease progression, and drug resistance emergence⁶.

While Ghana currently has 9 functional Roche Polymerase Chain Reaction (PCR) machines for HIV VL testing, the uptake of VL testing in Ghana has to date been low. In 2016, only 17,044 of the estimated 100,665 clients on ART had at least one VL test done (Table 1).

³ National HIV Prevalence and AIDS Estimates & Projections Report. 2016.

⁴ 2016 Annual Report. NACP, GHS

⁵ Guideline for Antiretroviral Therapy in Ghana. 2016. NACP, GHS

⁶ WHO 2015. Consolidated Guideline for treatment of Persons Living with HIV

Table 1: Viral Load Tests Conducted per Region in 2015 and 2016

Regions	On treatment in 2015	VL Tests Done (2015)	VL Tests Done (2016)
Ashanti Region (AR)	21882	739	4072
Brong Ahafo Region (BAR)	11304	571	1372
Eastern Region (ER)	11942	1097	1859
Greater Accra Region (GAR)	18836	5952	6605
Western Region (WR)	7545	120	893
Northern Region (NR)	2900	487	407
Upper East Region (UER)	2865	61	No data
Upper West Region (UWR)	2106	No data	No data
Volta Region (VR)	6740	22	500
Central Region (CR)	2993	567	1336
Totals	89113	9616	17044

The low uptake of VL testing to date is attributable to multiple factors such as the poor utilization of VL by clinicians, poor co-ordination of VL testing services, lack of a structured sample referral and results transmission system, workload and competing demands on laboratory personnel, weak clinical monitoring and evaluation of patients on ART, equipment malfunction, power fluctuations, reagent stock-outs and the absence of a VL scale up plan.

To effectively improve VL testing in Ghana, these multiple challenges must be addressed in a comprehensive and concerted manner. The current lack of a structured sample referral and results transmission system must, of necessity, be rectified and proper coordination of systems and range of activities that will culminate in the success of VL testing put in place. The procedures for collection, processing and transportation of samples to the regional and National centers for testing, must be clearly defined, tracked, monitored and appropriately supervised, while a framework is established to enable patient results to be sent back for clinical decision and patient monitoring in a timely manner. To make the VL testing system more robust and efficient, instances of laboratory reagent stock outs must be reduced to the barest minimum, and on-going equipment care and maintenance schedules are strictly being adhered to.

The Ministry of Health and the GHS, in collaboration with their development partners, are of the common understanding that developing a VL load Scale Up and Operational Plan is required to improve the overall uptake and utilization of VL testing services in Ghana. This Plan will provide the base and reference

point of a well-coordinated and efficient VL testing scale up, align with the National Strategic Plan and 90-90-90 Roadmap, and reflect the VL testing algorithm adopted by Ghana for the attainment of its goals for HIV management. The National AIDS/STI Control Programme recognizes the need for VL testing expansion in order to achieve the 90-90-90 target and improve the utilization of HIV services for the benefit of all PLHIV.

Current Status of VL Testing Programme in Ghana

At present, the VL testing programme for ART delivery in Ghana is being administered through the use of 9 Roche CobasAmpliPrep/Taqman 48 PCR (Taqman 48) machines located in 9 of the 10 regions of the country namely Brong Ahafo, Greater Accra, Central, Volta, Eastern, Northern, Ashanti, Western and Upper East. These machines were procured in early 2010 and are also used for HIV DNA-PCR Early Infant Diagnosis (EID) testing. Together, they can perform a total of 64,512 VL tests per year when operating optimally. However, by virtue of aging and 'wear & tear', their efficiency is fast diminishing. Prolonged equipment malfunction due to challenges with maintenance and repair support, electrical power interruptions, lack of sample referral and results transmission systems have hindered the capacity of the VL testing programme. By the year 2020, four of the units are likely to be permanently non-functional.

VL testing capacity has also been adversely affected by shortages, stock-outs and expiration of reagents associated with logistical issues in the reagent supply chain due to limited use of tools for forecasting and quantification of laboratory reagents at the national level. Currently, commodities are distributed using a push system and not strictly based on reported consumption reports.

There are currently 18 trained laboratory staff, on average 2 per testing site, conducting VL testing. But in order to provide VL testing at full instrument capacity and without service interruption, 3 laboratory personnel are required per site. While all existing staff have received technical training in VL testing currently, there is no standardized established technical training and competency assurance programme for newly hired and continuing staff.

Ghana has implemented a laboratory quality management system in 15 laboratories using the Strengthening Laboratory Management Toward Accreditation (SLMTA) tool. Of the 9 operational VL testing laboratories, 7 have completed the SLMTA training and were assessed by African Society for Laboratory Medicine (ASLM) using the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist with star ratings ranging from 2 to 4 (out of 5). However, since the SLMTA programme ended in 2015 these laboratories have not been assessed and their level of implementation of quality management systems have fallen back.

Also, the 9 VL testing laboratories are registered for an external proficiency testing programme with AfriQuaLab, a CDC supported laboratory based in Senegal, in which they perform satisfactorily. However, there is no inter-laboratory comparison testing system in place in the country.

Information management gaps also limit the VL testing programme. VL test requisition is done using general laboratory request forms that exclude VL specific data needed for patient monitoring, programme monitoring and evaluation. In addition, there are neither standardized VL registers at referring facilities nor laboratory registers for VL result entry. In addition, reporting of VL test results are not standardized across the system. The National AIDS/STI Control Programme, in collaboration with CDC, has implemented Basic Laboratory Information System (BLIS) as a tool for laboratory data management for VL and EID to feed information into the District Health Information Management System-II (DHIMS-II) and E-tracker, which are national monitoring and evaluation platforms.

A poor utilization of VL by clinicians and poor co-ordination of VL testing services also contributes to the low VL coverage of ART patients. The VL testing programme is managed as part of an integrated system of the comprehensive care for PLHIV from the national level through to the peripheral level. At the facility level, clinicians review the patient and make a request for the test. The patient is then assisted by nurses and caregivers to locate the testing laboratory where the sample is collected and either tested or referred for testing. The district level and regional coordination teams of the NACP/GHS are only involved when there is a challenge with the testing laboratory and clients are in need of assistance.

Ghana currently does not have a VL scale up plan. Likewise, there is no standardized VL Monitoring and Evaluation (M&E) plan to monitor and track key indicators, including viral suppression, which is the third 90 of the UNAIDS 90-90-90 aspirational targets. The available plans are insufficient for tracking key outcomes of the 90-90-90, thus concentrating more on above site level activities and indicators. This does not address facility level gaps and challenges within the systems.

SWOT Analysis of VL Testing Programme

A SWOT analysis of the VL testing programme (Table 2) reveals a number of key challenges and gaps that must be bridged with an intervention that is capable of achieving 2020 VL testing Programme goals.

1. There is currently no VL testing scale up plan to achieve these goals. The development of a plan will need to address a number of issues relating to testing capacity. These include insufficient numbers of functional VL testing platforms, service interruptions due to equipment malfunction and reagents stock-outs, insufficient testing staff, inadequate training of staff and high rates of attrition among these staff. Remediation of these issues is complicated by the lack of a continuous quality improvement scheme and a weak monitoring and evaluation programme.

2. There is a lack of logistics and transportation support from facilities as well as district and regional health directorates and no structured specimen referral system and results transmission system in place.

3. There is weak coordination between various service delivery facility levels and non-adherence to VL testing policy by clinicians and other clinical care providers.

Table 2: SWOT Analysis of VL Testing Programme

STRENGTHS	WEAKNESSES
<p>Equipment</p> <ul style="list-style-type: none"> • Nine (9) functional Taqman 48 PCR machines located in Nine regions. • Service contract available at the national level. 	<p>Equipment</p> <ul style="list-style-type: none"> • Non-availability of structured maintenance schedule. • Slow response to service calls (Roche). • Unstable power supply. • Frequent breakdown of the equipment. • Servicing parts are not readily available in-country. • Poor humidity and temperature control
<p>Human Resource</p> <ul style="list-style-type: none"> • Technical personnel available to operate the machines. • Roche Engineering personnel available to service the equipment. 	<p>Human Resource</p> <ul style="list-style-type: none"> • Lack of continuous training to cater for attrition of staff. • Laboratory Staff attrition. • Poor coordination among caregivers for VL testing. • GHS Engineering staff not trained to troubleshoot or service equipment.

<p>Logistics</p> <ul style="list-style-type: none"> • Availability of reagents and consumables. • Good reagents and consumables storage facilities available. 	<p>Logistics</p> <ul style="list-style-type: none"> • Poor Logistics Management Information System (requisition, transportation, storage, disposal and reporting) resulting in occasional stock-out and expiry of reagents.
<p>Specimen referral and results transmission</p> <ul style="list-style-type: none"> • Good inter-town road network. • Good communication means. • Good laboratory network. 	<p>Specimen referral and results transmission</p> <ul style="list-style-type: none"> • No structured specimen referral system and results transmission system in place. • Lack of systems that connect the laboratory information system with clinical sites for site and patient VL test monitoring and targeted identification of patients with virologic failure. • Lack of existing site level data utilization for clinical mentoring efforts directed at site level VL performance and follow up of patients with virologic failure. • Poor co-ordination of the VL testing system and processes within clinics and between clinics and laboratories • No VL testing Scale-up plan to match national strategic plan.
<p>Quality Assurance External quality assurance programme in place.</p>	<p>Quality Assurance</p> <ul style="list-style-type: none"> • Lack of VL testing Monitoring and Evaluation plan. • Limited clinical guidelines, SOPs and job aids for routine viral load monitoring. • Lack of accreditation for VL testing laboratories.
<p>OPPORTUNITIES</p>	<p>THREATS</p>
<ul style="list-style-type: none"> • Commitment from development partners to support Laboratory strengthening and capacity building. • Establishment of AIDS fund under the new GAC Act 938 is a potential source of future funding for national HIV strategic plan. 	<ul style="list-style-type: none"> • Unstable power supply (electrical wiring audits at all sites). • Dwindling donor funding support coupled with inadequate Government budgetary allocation for national HIV strategic plan. • Non-adherence to policy guidelines for Viral Load testing by service providers.

<ul style="list-style-type: none"> • Possibility of using GeneXpert and other Point of Care equipment at district and sub-district levels. • Training and research support. • Significant momentum catalyzed from global, regional and local demand for action on routine viral load monitoring. 	<ul style="list-style-type: none"> • Non-prioritization of transfer of technology for equipment management.
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VL Testing Programme 2020 Targets and Projections

With the adoption of the 2020 global UNAIDS 90-90-90 aspirational targets by Ghana, the need for an effective VL measurement of ART patients becomes not only relevant for patient monitoring, but also a vital means of measuring the overall treatment interventional outcomes. The targets set out under this new global drive, which aims at eliminating AIDS by 2030 are: (a) 90% of people living with HIV should know their HIV status by 2020 (b) 90% of people who know their HIV status are to be on ART by 2020 and (c) 90% of people receiving ARV treatment to achieve viral suppression within 12 months of initiation of therapy by 2020.

These targets form part of the basis of the current drive towards immediate ART enrollment following HIV diagnosis and using VL as the primary means of monitoring clients on ART. This therefore imposes a greater responsibility on Ghana to significantly improve VL testing capacity, testing systems and uptake. Only 9,616 of the 89,113 PLHIV on ART by end of 2015, received VL testing within the year. In 2016, a total of 20,497 new clients were initiated on ART, bringing the total cumulative number of clients on ART to 100,665. During the period of 2016, however, only 17,044 (16.9%) VL tests were conducted on both old and newly initiated clients⁷.

The estimated prevalence of HIV amongst the general population for 2016 was 1.6% with an estimated number of persons living with HIV being approximately 290,000⁸. Based on the 2016 Spectrum Outputs of National HIV Prevalence and AIDS Estimates & Projections, the HIV population was projected to experience slight increase from 293,805 in 2016 to 316,994 in 2020, as per Table 3 below.

⁷ NACP Service Data, 2016

⁸ 2016 National HIV Prevalence and AIDS Estimates & Projections Report

Table 3: Estimated and Projected PLHIV, ART Patients and VL Test Volumes

YEAR	2015	2016	2017	2018	2019	2020
Estimated Number of PLHIV	274,562	293,805	299,110	304,459	310,514	316,994
90% who know HIV status						285,295
90% who know status to be on ART	81,988	100,665	100,665 + 48,285 = 148,950	148,950 + 48,285 = 197,235	197,235 + 48,285 = 245,520	245,520 + 48,285 = 293,805
VL testing for New Clients up to 1 year (2x48,285)			96,570	96,570	96,570	96,570
VL testing for Clients beyond 1 year on therapy			100,665	197,235	245,520	293,805
Total Number of VL tests per year	9,616	17,044	197,235	293,805	342,090	390,375

Taking the 2016 National HIV Prevalence and AIDS Estimates & Projections and the 90-90-90 targets into consideration, there are anticipated to be 316,994 PLHIVs in 2020, of which 390,375 are expected to be on ART. Considering that the actual number of PLHIVs on ART at end of 2016 was 100,665, it is anticipated that there will be the need to enroll and retain 193,140 new clients on ART in Ghana, as well as the need to improve on the numbers of lost to follow-ups and deaths between 2017 and end of 2020. This will require enrolling an annual average of 48,285 new clients on ART over the next four years, as well as putting measures in place to minimize loss-to-follow up and death. As per Ghana's National ART Guidelines, each newly enrolled client will require two VL tests within the first year of initiation at 6 months intervals; the first test being done 6 months after initiation. With the estimated new ART enrollment of 48,285, it is expected that an average of 96,570 VL tests will be conducted each year

only for newly enrolled ART clients. Clients who have also been on treatment for more than 12 months will be required to have at least one VL test done per year.

Based upon these projections, the annual volume of VL tests that will need to be performed 2017-2020 are 197,235 in 2017; 293,805 in 2018, 342,090 in 2019 and 390,375 in 2020 (Table 3). This implies that a total of 1,223,505 VL tests will need to be conducted between 2017 and 2020 to meet Ghana's programmatic goals. Based upon these projections, the annual number of VL tests to be conducted for the next 4 years will increase significantly from current levels given that 80% of the total testing capacity of the current 9 Taqman 48 instruments is dedicated to VL testing and the remaining 20% taken up by EID testing, the testing capacity of Ghana's current equipment will be significantly inadequate for this dramatic expansion of testing services.

Programme Needs to Meet 2020 VL Testing Programmatic Goals

The National VL testing goal is to attain 95% coverage ART patients by 2020. Forecasted needs to bridge existing programmatic gaps to meet this goal include:

1. VL Demand Creation

To meet the 2020 VL targets, demand creation for clinicians and other health care cadres such as Nurse Prescribers, primary counselors, community health care workers, expert patients and PLHIV. Demand creation activities such as orientation, stakeholder meetings, trainings and refresher courses will be provided.

2. Test Equipment

The annual testing capacity of Roche testing platforms is illustrated in Table 4. To meet the 2020 VL programme goals of 95% coverage of ART patients, the country-wide system will require an annual capacity of 390,375 VL tests. It is planned that this testing will be performed using twelve (12) Roche PCR platforms (4

Taqman 48 and 8 Taqman 96 Platforms) distributed across 12 test sites in 10 regions (Table 5) providing a total testing capacity of 258,048 VL samples /year (32,256 + 225,792 as per Table 4). Three of these centers namely; Korle Bu Teaching hospital, Komfo Anokye Teaching hospital and the Tamale Public health laboratories covering the southern, middle and the northern belts respectively of the country will be equipped to serve as centres of excellence in viral load and DNA PCR testing and ultimately take up the entire testing needs of the country. If needed, additional capacity may be added using GeneXpert.

Table 4: Annual Test Capacity of Planned Roche COBAS Taqman 48 and 96 (147 test) Platforms

	Roche Cobas Taqman 48		Roche Cobas Taqman 96 (147 tests)
	Tests (Test + Controls)	Tests (Tests only)	Tests (Tests only)
Tests/day/platform	48	42	147
Tests/week/platform (4 Days)	192	168	588
Tests/month/platform (4 weeks)	768	672	2352
Test/year/platform (12 months)	9216	8064	28224
Total test capacity of 4 Taqman 48 and 8 Taqman 96 (147 test) platforms	36,864	32,256	225,792

Table 5: Current and Planned Distribution of Roche Taqman VL Test Platforms

REGION	2017 (current)	2020
Greater Accra	1 Taqman 48	2 Taqman 96
Ashanti	1 Taqman 48	2 Taqman 96
Brong Ahafo	1 Taqman 48	1 Taqman 96
Eastern	1 Taqman 48	1 Taqman 96
Volta	1 Taqman 48	1 Taqman 96
Western	1 Taqman 48	1 Taqman 96
Upper East	1 Taqman 48	1 Taqman 48
Upper West	0	1 Taqman 48
Northern	1 Taqman 48	1 Taqman 48
Central	1 Taqman 48	1 Taqman 48
Total	8 (Taqman 48)	12 (8 Taqman 96; 4 Taqman 48)

3. Equipment Maintenance System

In order to meet 2020 annual VL testing targets, it will be essential that all nine test platforms are supported by a reliable maintenance programme. It is intended that the 4 Taqman 48 platforms, currently owned by the Ghana Health Services, will be supported by a maintenance contract with the vendor and that the 9 Taqman 96 instruments, will be acquired through lease/placement agreements and will be supported by the vendor through the terms of the lease/ placement agreements.

Equipment performance is affected by environmental conditions such as high humidity, temperature and dust. VL laboratories will be supported to ensure laboratory environmental conditions are maintained to ensure optimal performance.

4. Supply Chain

Currently laboratory supplies are distributed through a parallel system. Laboratory reagents stored at the central level are allocated and distributed to the Regional Medical Stores (RMSs) or directly to the testing facilities.

Due to inadequate cold chain storage facilities at some Regional Medical Stores (RMS), they are unable to store commodities and so to prevent damage of these commodities, they are sent directly to the testing sites using available means. Even though there is the availability of a logistics tool for collection of consumption data this is not utilized. As a result, there are challenges in the reporting

of consumption data from the testing sites to the region and then the central level.

By 2020, a supply chain and logistics operation will be required that is capable of providing supplies and reagents necessary for the performance of 390,375 VL tests annually (across 12 testing sites using Taqman platforms and 130 sites using the GeneXpert platforms) with minimal interruption of testing or disruption of turnaround times for specimens due to shortages and stock-outs.

5. Human Resources

By year 2020, 36 well trained and competent laboratory personnel (3 per test site) will be required to support the VL load testing targets for the country; this will be achieved by the hiring and training to competency of 18 additional lab VL testing staff, to support 12 test sites by 2018 (Table 6). To support these 36 testing personnel, a standardized training programme for re-assigned personnel and a continuing education/refresher training programme for existing personnel will be developed and implemented throughout the system.

6. Specimen Referral and Result Delivery System

By 2020 a standard specimen and result delivery system must be in place for all 10 regions (including the 3 Teaching hospitals: Komfo Anokye Teaching Hospital, Korle-Bu Teaching Hospital and Cape Coast Teaching Hospital) in the country to

support the VL testing programme. This will require an initial and continuing on-going training in courier services.

Table 6: Projected Lab Testing Staff Needs per Region

VL Testing Site	Current VL Load testing staff	Additional staff needed			TOTAL VL Load Testing Personnel (2020)
		2018	2019	2020	
Western Region	2	1	0	0	3
Greater Accra Region	0	3	0	0	3
Korle-Bu Teaching Hospital	2	1	0	0	3
Komfo Anokye Teaching Hospital	2	1	0	0	3
Ashanti Region	0	3	0	0	3
Northern Region	2	1	0	0	3
Brong Ahafo Region	2	1	0	0	3
Eastern Region	2	1	0	0	3
Cape Coast Teaching Hospital	2	1	0	0	3
Volta Region	2	1	0	0	3
Upper East Region	2	1	0	0	3
Upper West Region	0	3	0	0	3
TOTAL	18	18	0	0	36

7. Information Management

PCR test machines will need to be interfaced with the BLIS data management system. In addition, standardized paper forms are required to support the VL testing data management (test request forms, lab data sheets, VL register, and test report forms).

8. Monitoring and Evaluation

Effective monitoring and evaluating tools are required to provide ongoing monitoring of targets and indicators used to measure progress and success of the scale-up plan as well as the performance of the 12 testing sites. Analyzed data are needed for identification of challenges and implementation of appropriate improvements.

b. GOAL, OBJECTIVES AND STRATEGIES OF VL SCALE-UP PLAN (VLSUP)

Goal of Viral Load Scale-Up Plan

The goal of the VLSUP is to ensure that all HIV clients on ART have access to routine VL testing in line with programmatic guidelines and national Strategic Plans by 2020.

Objectives of the Scale up Plan

The objectives of this plan are to:

1. To ensure a coordinated VL testing scale-up in Ghana from the current 16.9% to 60% by the end of 2018 and universal access (>95% coverage) by 2020.

2. To support resource mobilization for VL Scale-up through highlighting the funding and systemic gaps that need to be closed in order to make this plan a success.

3. To ensure all laboratory staff assigned for VL testing are properly trained and deemed competent to perform their duties with respect to specimen handling, processing, testing, transporting, data management and reporting.

4. To select appropriate technology for VL and adequate and continuous supplies and reagents.

5. To develop and implement an effective M&E framework and plan.

Overview

Considering the current state of under-performance of VL testing in the country coupled with the need to scale up services to reach all clients accessing treatment at all ART sites across the country it is particularly critical that 1) strategies are put in place to address the current inherent weaknesses in the existing VL testing system, 2) to initiate new approaches to surmount challenges preventing the optimal utilization of existing VL machines and 3) to develop a scale-up plan to provide guidance and protocol for overall improvement in the universal provision and utilization of VL testing services across the country with a robust co-ordination and M&E framework.

A phased approach would be adopted for this scale up as outlined below:

Phase 1 (2017)

- Finalize and approve the VSUP.
- Map out and implement an effective sample referral and results delivery system.
- Develop Standard Operating Procedures (SOPs) and other guidelines for VL testing.
- Build capacity of laboratory personnel on SOPs and guidelines.
- Replace and/or add equipment for four (4) regions [GAR, AR, ER, WR].
- Establish of M&E system.
- Initiate and sustain VL testing demand Creation.

Phase 2 (2018)

- Build capacity for all care providers on all implementation strategies.
- Improve on data management and M&E systems.
- Replace equipment for three (3) regions [UER, BA, NR].
- Establish Quality Management System (QMS) and VL accreditation.
- Establish the concept of VL centres of excellence.

- Evaluate addition of GeneXpert platform for VL testing.
- Start setting priorities and themes for operational research.

Phase 3 (2019)

- Equipment replacement for two (2) regions [VR, CR].
- Develop and implement a plan for using GeneXpert for VL testing.
- Disseminate lessons and Carry out new operational research.
- Continue capacity building of service providers to fill new gaps.

Phase 4 (2020)

- Evaluate performance of systems.
- Disseminate research findings and share best practices through well established country dialogue platforms.
- Revise the VL Scale-up plan for the post 2020 period.

SPECIFIC OBJECTIVES AND STRATEGIES

Objective 1:

Programme Management

To establish an effective programme management system that includes task teams at all levels to effectively oversee the implementation of the plan which will be linked to an overarching technical working group (TWG).

Strategies

- **Strategy 1.1:**

Form VL Task Teams, which will comprise the Regional HIV coordinator, Regional Laboratory Focal Point, Medical laboratory scientist (MLS) at Testing Lab, and the Data Officer's Representative. This team is to ensure logistics are in place and requests for the tests are made. It shall address immediate issues and perform monitoring of activities.

- **Strategy 1.2:**

Establish a TWG: Programme Officer at NACP (preferably the National Laboratory Focal Person), 3 MLSs representing three (3) zones in the country [Northern, Middle, and South], Regional Coordinators Representative, Procurement and Supply Representative, and M&E Representative. The TWG will meet quarterly to review progress of implementation in the first year and bi-annually in subsequent years. The TWG will define roles and responsibilities of all caregivers through the capacity system to ensure a smooth scale up of VL testing.

Objective 2:

Install Equipment

To install twelve (12) functional and well-maintained Roche Taqman machines and, if needed, 130 GeneXpert machines will support the VL load testing programme targets by 2020.

Strategies

- **Strategy 2.1:**

Acquire 4 new PCR machines to replace existing Taqman 48 platforms in a phased manner: In phase one (2017), four Taqman 96 (147 test) platforms will be acquired for the 4 priority regions (2 in Greater Accra and 2 in Ashanti regions) to replace the current units. The current two existing machines that are freed up will then be moved to the Upper West and Upper East Regions in 2017, providing testing sites in all ten regions. In phase two (2018), four more Roche Taqman 96 platforms will be acquired to replace the older, smaller units in 4 regions.

- **Strategy 2.2:**

Utilize maintenance contracts for the Taqman 48 platforms and lease agreements (that include maintenance) for Taqman 96 to ensure that the machines are well maintained and functioning optimally.

- **Strategy 2.3:**

Train and assess competency of laboratory staff.

- **Strategy 2.4:**

Develop SOPs for GeneXpert platforms to provide VL testing, as needed

- **Strategy 2.5:**

Develop a decommission strategy for old, unusable platforms.

Objective 3:

Supply Chain Management and Logistics

Ensure that sufficient supplies and reagents are available at all testing sites to permit the testing of 390,375 VL specimens in 2020, meeting established turnaround time (TAT) (3 days) for 90% of specimens.

Strategies

- **Strategy 3.1:**

Establish a system to ensure regular supply of reagents to meet the testing needs of the country.

- **Strategy 3.2:**

Build the capacity of personnel handling laboratory commodities in logistics management and information system.

- **Strategy 3.3:**

Develop a system to support the in-country distribution of commodities from the central level to the regional medical stores and then to the testing sites.

- **Strategy 3.4:**

Collaborate with the Food and Drugs Authority (FDA) to establish a system for post-market surveillance testing of commodities in order to assure the quality of products being purchased.

Objective 4:

Human Resources and Training

To have 36 VL testing staff employed at the 12 test sites by the end of 2020 and have a structured annual continuous training programme in place for all VL testing staff and all specimen courier staff.

Strategies

- **Strategy 4.1:**

Develop standardized annual and continuous training programme for all VL testing staff

- **Strategy 4.2:**

Reassign 18 new VL testing staff to be placed in testing sites as indicated in table 1.

- **Strategy 4.3:**

Implement training of laboratory staff, assess and maintain staff competence.

- **Strategy 4.4:**

Training of ART staff on sample collection, processing and transportation techniques.

Objective 5:

Specimen Referral and Result Transmission

To implement a specimen referral and results transmission system for VL testing that will support an increase in annual test volume from 17,044 specimens in 2016 to 390,375 specimens by 2020, meet specimen handling requirements and reduce specimen turnaround time to less than or equal to 14 days by 2020.

Strategies

- **Strategy 5.1:**

Conduct an assessment of all VL testing sites using the VL score card.

- **Strategy 5.2:**

Develop Geographic Information System (GIS) maps and demarcate sample transportation routes of all 245 ART centers in Ghana.

- **Strategy 5.3:**

Pilot two modes of sample referral and result submission transmission system for 6 months in WR and ER using two modes of transport: a courier system and local transportation system.

- **Strategy 5.4:**

Use lessons learnt from pilot to review and modify the sample referral and results transmission system.

- **Strategy 5.5:**

Scale up the sample referral and result submission system in a stepwise approach.

Objective 6:

Quality Assurance Programme

To establish an effective quality assurance system across all VL testing laboratories to assure the quality of patient test results.

Strategies

- **Strategy 6.1:**

Perform baseline quality assessment in all the VL testing labs.

- **Strategy 6.2:**

Implement and monitor Internal Quality Control (IQC) and External Quality Assurance (EQA).

- **Strategy 6.3:**

All laboratories to monitor quality indicators.

- **Strategy 6.4:**

Train all staff at all laboratories in QMS.

Objective 7:

Laboratory Information Management

To establish a robust, standardized and fully operational laboratory information system for VL testing services in all VL testing laboratories to feed information into DHIMS and E-tracker systems by December, 2020.

Strategies

- **Strategy 7.1:**

Incorporate Viral Load Management System (VLMS) into BLIS.

- **Strategy 7.2:**

Interface all PCR VL test instruments with BLIS, DHIMS-2 and e tracker.

- **Strategy 7.3:**

Develop standardized paper-based forms and registers (lab request forms, VL sample referral register, lab register, test report form).

Objective 8:

Monitoring and Evaluation

To provide an effective M&E framework and tools to evaluate the success of implementation of the VL scale-up plan through quarterly reporting.

Strategies

• **Strategy 8.1:**

Develop programme indicators and tools to monitor and access implementation targets set in the scale up plan.

• **Strategy 8.2:**

Monitor indicators of VL testing monthly.

- Collate and analyze data and write quarterly reports.
- Report shared with MOH/GHS and stakeholders/partners.
- Review reports at bi-annual meetings.
- Develop and implement improvement strategies as appropriate.
- Strengthening BLIS to include all laboratory associated indicators.
- Train testers on monitoring indicators and taking corrective actions.
- M&E focal persons trained to produce monthly summary reports.
- Monthly review and follow-up of summary reports.

Evaluation

- Annual/multiple year evaluation.
- Data Quality Analysis.
- Cohort Analysis.
- Quality of Service Assessment.

Programme-based indicators

- Number of HIV patients (patients on ART).
- Proportion of VL test done on newly diagnosed / long term ART clients.
- Number of facilities doing VL testing for clients on ART.
- Number of clients with viral suppression at 6 months after ART initiation.
- Number of clients with viral suppression at 12 months after ART initiation.
- Total Number virally suppressed.

Lab-based indicators

- Number of VL test conducted per month per site.
- Number of results returned to requesting facilities.
- Turn-Around-Time from sample collection to receipt of results.
- Number of rejected samples.
- Number of days of equipment breakdown.
- Number of preventive maintenance sessions conducted.
- Number of days QC failed.
- Proficiency Testing: acceptable or not acceptable.
- Number of days of stock-outs of VL testing commodities.

b.

ACTIVITIES OF VL SCALE UP PLAN

GHANA OPERATIONAL PLAN MATRIX FOR LABORATORY VIRAL LOAD SCALE UP TESTING (2017 - 2020)																		
Phase 1: 2017; Phase 2: 2018; Phase 3: 2019; Phase 4: 2020																		
OBJECTIVE 1: To establish an effective program management system																		
Strategy 1.1: Establish VL task teams in the regions and teaching hospitals																		
1.1	ACTIVITY	OUTPUT/ PRODUCT	INDICATOR VERIFICATION	RESPONSIBLE	PARTNERS	COST	2017			2018			2019					
							Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2		
1.1.1	ToR for task teams to be developed during a one day meeting by a team of 4	TOR developed	Copy of TOR	NACP Laboratory focal person	PM-NACP, CEOs Teaching Hosp., DG-GHS, RDHS				X									
1.1.2	Establish 12 VL task teams comprising four (4) members each	12 Task teams established	Number of task team formed documented	NACP Laboratory focal person					X									
1.1.3	Conduct monthly task team meeting and report to the TWG	Monthly task team meetings held	Number of Task team meetings held and reports received	NACP Laboratory focal person					X									X
Strategy 1.2: Establish a National VL Scale-Up TWG																		
Phase 1: 2017; Phase 2: 2018; Phase 3: 2019; Phase 4: 2020																		
1.2	ACTIVITY	OUTPUT/ PRODUCT	INDICATOR VERIFICATION	RESPONSIBLE	PARTNERS	COST	2017			2018			2019					
							Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2		
1.2.1	ToR for TWG to be developed during a one day meeting by team of 4 persons	TOR developed	Copy of TOR developed	NACP Laboratory focal person	DG-GHS, PM-NACP, RDHS					X								
1.2.2	Identify 11 persons to constitute TWG and notify them	11 Persons identified and notified	Letter of notification	NACP Laboratory focal person						X								
1.2.3	Establish and inaugurate VL TWG	VL TWG established and inaugurated	Report of inaugural VL TWG meeting	NACP Laboratory focal person							X							

1.2.4	Conduct quarterly TWG meetings and report feedback to task teams	Quarterly TWG meetings held	Number of meetings held and reports received by task teams	NACP Laboratory focal person					
									X
OBJECTIVE 2: To have 12 functional Roche Taqman and 130 GeneXpert machines operating optimally and well maintained by 2020									
2.1 Strategy 2.1: Establish lease agreements to replace existing platforms in a phased manner									
2.1.1	Prepare and obtain approval for technical and performance specification documents for the equipment	Technical and performance specification documents available	Specification documents prepared and approved	Director CEU	NACP, P&S-MOH: co-ordination, The Global Fund-technical support,			X	
2.1.2	Prepare order form based on approved technical documents	Order form completed	Order form submitted to procurement agent	Procurement officer, P&S	NACP- co-ordination, The Global Fund-technical support		X	X	X
2.1.3	Prepare the lease agreement	Lease agreement signed and contract established	copy of lease agreement	Procurement agent	CEU (GHS), NACP, P&S-MOH- co-ordination, The Global Fund-technical support,			X	
2.1.4	Install 4 machines in Korle-bu, GAR, KATH, AR	4 Machines supplied, installed and functional	No. of Functional machines at GAR, AR, K-bu, KATH	Director CEU	NACP, P&S-MOH: co-ordination, The Global Fund-technical support,				

2.1.5	Install 4 machines in CR, BAR, VR and ER	4 Machines supplied, installed and functional	No. of Functional machines at CR, BAR, VR, ER	Director CEU	NACP, P&S- MOH- coordination, The Global Fund- technical support,							X	X
2.1.6	Install HVAC at 9 VL testing site	VL sites have temperature and humidity controls	Number of sites having temperature and humidity controls	Director CEU	NACP, P&S- MOH- coordination, The Global Fund- technical support							X	X
2.1.7	Service and certify 9 Biosafety cabinets and establish annual service contracts	Properly functioning biosafety cabinets with service contracts	Number of certified biosafety cabinets and number of service contracts	Director CEU	NACP, P&S- MOH- coordination, The Global Fund- technical support							X	X
2.2	Strategy 2.2: To ensure that current machines are well maintained and functioning optimally												
2.2.1	Develop and disseminate tool to monitor preventative maintenance performance of equipment	Tool available in 12 testing sites	Number of sites with monitoring tool in use	NACP Laboratory focal person; laboratory managers	MOH, GF							X	
2.2.2	Monitor and ensure compliance with lease agreement with Roche on the maintenance of the new platforms	Service maintenance carried out	Number of equipment maintenance reports	NACP Laboratory focal person	MOH, GF							X	X

2.3		Strategy 2.3: To train laboratory staff, assess and maintain competence					2017	2018	2019
2.3.1	Train 3 lab staff from each of the 12 sites on VL testing, equipment maintenance, logistics management	Trained and competent lab staff in 12 sites	Number of staff trained, number of sites with trained staff	NACP Laboratory focal person	CDC, NACP GF, Roche				
2.4		Strategy 2.4: Develop SOPs for GeneXpert platforms to provide viral load testing, as needed					2017	2018	2019
2.4.1	Establish a task team to assess adequacy of Taqman VL testing capacity and report on findings	Team report on status of testing of testing capacity	Report completed and submitted to NACP	NACP Laboratory focal person	CDC, NACP GF				
2.3.2	Development of SOPs for VL testing on GeneXpert, if report deems additional testing capacity is needed	Required SOPs reviewed and approved	Number of required SOPs revised and approved	Lab focal person	CDC, NACP GF				
2.5		Strategy 2.5: Establish decommission procedure for old and usable platforms					2017	2018	2019
2.5.1	Develop decommission plan and SOP	Decommission plan and SOP developed	Number of sites with SOPs	NACP Laboratory focal person			x		

2.5.2	Identify 4 platforms to be decommissioned	4 platforms identified for decommission	Number of platforms identified															
2.5.3	Decommission 4 platforms	4 platforms decommissioned	Number of platforms decommissioned															
OBJECTIVE 3: To ensure that reagents and consumables for 242,801 viral load test are available by 2020																		
3.1	Strategy 3.1: To provide adequate and continuous supply of reagents to meet VL testing targets																	
	ACTIVITY	OUTPUT/PRODUCT	INDICATOR/VERIFICATION	RESPONSIBLE	PARTNERS	COST	2017			2018			2019					
							Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2		
3.1.1	Conduct National quantification and develop supply plan for commodities	Quantification determined and supply plan report available	Quantification and supply plan report available	PSM focal person, NACP							X							
3.1.2	Order form completed and submitted to the procurement agent	Order form prepared and submitted	Order form submitted on time	P&S procurement officer	Procurement agent, NACP,						X							
3.1.3	Identify supplier and sign contract	Supplier identified and contract signed	Copy of signed contract	Procurement agent GF	NACP, MOH						X				X			
3.1.4	Orders are delivered on a quarterly basis to the Central warehouse	Orders received at the warehouses	Number of orders received	PSM focal person, NACP	MOH						X				X			X

3.1.5	Develop consumption forms to be completed by testing sites bi-monthly and bi-monthly reports compiled	Bi-monthly reports from testing sites and compiled report completed	Number of sites providing monthly consumption data reports	Laboratory focal person, NACP PSM focal person, NACP	Laboratory focal person, NACP						X	X	X	X	X	X
3.1.6	Write annual consumption report	Report written	Report available	PSM focal person, NACP							X					
3.2	Strategy 3.2 Conduct training in 2017 for all laboratory personnel in logistics management										2017	2018	2019			
3.2.1	To train 36 laboratory personnel (3 persons per site)	36 trained laboratory personnel	Number of laboratory personnel trained per site	Lab focal person, NACP						X						
3.3	Strategy 3.3: Support 10 Regional Medical Stores (RMS) to distribute commodities to testing sites										2017	2018	2019			
3.3.1	Develop and submit distribution plan for reagents from the RMS to testing sites	Distribution plan approved	Distribution plan implemented by RMS.	RMS managers	NACP-coordination					X	X	X	X	X	X	X
3.3.2	Provide financial support to the 10 RMS to ensure ongoing distribution of supplies	Financial support provided	Number of RMS receiving financial support	Accounts unit head, NACP						X	X	X	X	X	X	X

3.3.3	Deliver commodities from the 10 RMS to 12 testing sites every 2 months	Commodities delivered to testing sites every 2 months	Number of sites receiving commodities as per site requests	10 RMS managers	RMS- send commodities to SDPs	X	X	X	X	X	X	X	X	X
3.4	Strategy 3.4: Undertake post market surveillance testing of commodities to assure quality of products						2017		2018		2019			
3.4.1	Develop Post Market Surveillance Plan and SOPs for VL reagents	Plan and SOPs developed	Plan implemented and reoperated	PSM focal person, NACP		X								
3.4.2	Train staff on SOPs	Staff trained	Number of staff trained	PSM focal person, NACP		X								
3.4.3	Post Market Surveillance procedures implemented as per plan	Plan implemented	Report of implementation	PSM focal person, NACP				X	X	X	X	X	X	X
3.4.4	Write annual report	Annual report available and reviewed	Annual report available	PSM focal person, NACP				X					X	X
	OBJECTIVE 4: Train 36 VL lab staff, develop and implement a structured continuous training program for VL scale up by 2020													
4.1	Strategy 4.1: Develop an annual continuous training program for all viral load sites						2017		2018		2019			
	ACTIVITY	OUTPUT/ PRODUCT	INDICATOR/ VERIFICATION	RESPONSIBLE	PARTNERS	COST	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
4.1.1	Review and revise training materials.	A Training curriculum developed	Curriculum available	Roche/NACP	NACPLab- oratory Fo- cal Person/ Roche			X						

4.3.3	Train 3 lab staffs from each of the 12 sites on logistics management (LM)	36 Trained and competent lab staff at 12 sites	Number staff trained in LM	Lab focal person	CDC, NACP GF, Roche											X	X		
4.3.4	Train 3 lab staff on Specimen Referral (SR)	36 Trained lab and competent staff at 12 sites	Number of staff trained in SR	Lab focal person	CDC; NACP														
4.3.5	Train 3 lab staff on use of BLIS	36 Trained and competent lab staff at 12 sites	Number of staff trained in BLIS	Lab focal person	CDC; NACP														
4.3.6	Train 3 staff from each site on QMS	36 Trained and competent lab staff at 12 sites	Number of staff trained in QMS	Lab focal person	CDC, NACP GF														
OBJECTIVE 5: Implement a sample Referral and results transmission system																			
5.1	Strategy 5.1: Conduct baseline assessment for 9 VL Testing Labs																		
	ACTIVITY	OUTPUT/ PRODUCT	INDICATOR	RESPONSIBLE	PARTNERS	COST	2017			2018			2019						
5.1.1	Select 6 assessors and conduct a 3 days training on the use of the existing assessment tool	6 assessors trained on use of tool	Number of assessors trained	Lab Focal Persons	NACP, CDC				X										
5.1.2	Notify 9 sites and conduct baseline assessment at all sites. 2 days per site.	Completed assessment for each site	Number of site assessment reports	Assessors, Lab Focal Persons	NACP, CDC	20,000			X										

								2017	2018	2019	
5.1.3	Develop final assessment report	Final assessment Report	Dissemination of Report	Assessors, Lab Focal Persons	NACP, CDC			x			
5.2	Strategy 5.2: Conduct GIS Mapping for all 245 ART sites										
5.2.1	Selection of a 10 member core team for GIS mapping. These team would be supported by Data Officers across all 245 ART sites	GIS mapping core team selected	Number of people selected	Lab Focal Persons	NACP, CDC, CERSIS-UG			x			
5.2.2	3 Day training and development of activity, worksheets and travel plan	GIS mapping team trained and worksheets/travel plans developed	Number meetings completed; worksheets completed	Lab Focal Persons	NACP, CDC, CERSIS-UG, Data Officers			x			
5.2.3	GIS Mapping at 245 ART sites	Completed worksheets	% completed worksheets	Lab Focal Persons	NACP, CDC, CERSIS-UG, Data Officers			x			
5.3.4	Develop database with GIS coordinates for all 245 ART sites and develop maps	Database and maps completed	% of sites with coordinates and mapped	Lab Focal Persons	NACP, CDC, CERSIS-UG			x			
5.3.5	Develop final activity report	Final report completed Funding identified	Final report reviewed and funding for pilot secured	Lab Focal Persons	NACP, CDC, CERSIS-UG, GF, UNAIDS			x			
5.3	Strategy 5.3: Pilot two methods of sample transportation and result submission at ER and WR										

5.3.1	Develop training materials (for couriers, drivers, lab staff, nurses, etc.), SOPs and sample transport forms.	Training materials, SOPs and forms developed	Number of training materials, SOPs and forms developed and printed	Lab Focal Persons	NACP, APHL, CDC																X			
5.3.2	MOU between MoH/GHS/NACP, EMS and Local transport Unions (GPRTU, PROTIA, VIP, STC)	Signed MOU	MoU implemented	PM	NACP, CDC, MoH, Local Transport Unions, EMS																X			
5.3.3	Procurement of commodities for sample transport system, 490 cold boxes, 2,450,000 zip lock bags, 50 low speed centrifuges, 20 freezers, 100 SMS printers	Logistics procured and distributed	Number procured and distributed: cold boxes, zip lock bags, centrifuges, Freezers procured and distributed	Lab Focal Persons	CDC, APHL, NACP																X			
5.3.4	Sensitization meeting for all stakeholders at ER and WR	Sensitization meeting conducted	Sensitization meeting completed and report available	Lab Focal Persons	GHS, NACP, CDC																X			
5.3.5	Train 20 transport union and courier staff on sample transportation, safety, documentation and storing of tracking forms (10 staff per region)	1 week training completed for drivers and courier staff	Number staff trained; number of transport unions with trained staff	Lab Focal Persons	NACP, GPR-TU, PROTIA, CDC, APHL																X			

						2017		2018		2019	
5.4 Strategy 5.4: Commence the pilot phase of the sample referral system for 6 months											
5.3.6	Train 192 ART site staff on sample collection, processing, storage and packaging, sample receipt, safety, documentation and processing (64 ART sites in ER and WR x 3 staff)	1 weeks (2 trainings x 1 week) training completed for staff of ART sites at ER and WR	Number staff trained; Number of sites with trained staff	Lab Focal Persons	NACP, CDC, APHL						
5.4.1	Use courier (EMS) and/or local transport unions for sample transportation and results delivery at the WR (31 sites). EMS is well established courier system in Ghana. They have their own fleet of cars and motor bikes that transport letters, etc. from all over the country.	Pilot phase completed after 6 months	Number of samples transported from ART sites to testing centres; ART sites sending samples; reports returned to ART sites; sample TAT; missing samples; missing results	Lab Focal Persons	NACP, CDC						
5.4.2	Electronic transmission of results: Email results delivery for 20 sites (10 sites in each region) and SMS results delivery using SMS printers for 20 sites (10 sites per region). Hard copy reports delivered	Electronic configurations completed; SMS printers installed	Number of results sent via emails; results sent via SMS; hard copies of results received; results missing/not received	Lab Focal Persons, LIS Team	NACP, CDC, CHIM						

			3 monitoring visits completed for each region	Number of evaluation visits, evaluation visit reports	Lab Focal Persons	NACP, CDC												
5.4.3	Monitor the sample referral system pilot		3 monitoring visits completed for each region	Number of evaluation visits, evaluation visit reports	Lab Focal Persons	NACP, CDC												
5.4.4	Data entry, analysis and write final pilot report		Final report drafted	Completed final report	Lab Focal Persons	CDC, NACP												
5.4.5	Final report dissemination		Dissemination meeting organized	Final report disseminated.	Lab Focal Persons	CDC, NACP, GF, UNAIDS, WHO												
5.5 Strategy 5.5: National Scale up of sample referral system to 4 additional regions (AR, GAR, BA, NR)																		
5.5.1	Distribute supplies to ART sites in AR, GAR, BA and NR. A total of 150 sites. Distribution will be done based on the number of sites per each region and commodities need		Supplies distributed	Number of cold boxes, zip lock bags, centrifuges, Freezers procured and distributed per site		CDC, APHL, NACP												
5.5.2	1 day sensitization meeting for all stakeholders in 4 regions		Sensitization meeting organized	Report of Sensitization meeting	Lab Focal Persons	GHS, NACP, CDC												
5.5.3	Train (retrain) 40 transport union and courier staff on sample transportation, safety, documentation and storing of tracking forms (10 staff per region)		4 x 1 week training completed for drivers and courier staff	Number of staff trained	Lab Focal Persons	NACP, GPRTU, PROTIA, CDC, APHL												

5.5.8	Monitor the sample referral for the 4 regions	Three monitoring visits completed for each region	Number of evaluation visits, evaluation visit reports	Lab Focal Persons	NACP, CDC					X	X
5.5.9	Data entry, analysis and develop of quarterly reports (per M&E plan)	Final report written	Final report available	Lab Focal Persons	CDC, NACP					X	
5.5.10	Review of reports	Reviews completed	Number of review meetings	Lab Focal Persons	CDC, NACP, TWG, Task Team					X	
Strategy 5.6: National Scale up of sample referral system to 4 additional regions (CR, UER, UWR, VR)											
5.6.1	Distribute sample referral supplies to ART sites in CR, UER, UWR, VR	Adequate supplies distributed	Number of cold boxes, zip lock bags, centrifuges, Freezers procured and distributed	Lab Focal Persons	CDC, APHL, NACP					X	
5.6.2	1 day sensitization meeting for all stakeholders in 4 regions	Sensitization meeting organized	Sensitization meeting completed	Lab Focal Persons	GHS, NACP, CDC					X	
5.6.3	Train (retrain) 40 transport union and courier staff on sample transportation, safety, documentation and storing of tracking forms (10 staff/region)	4 x 1 week training completed for drivers and courier staff	Number of staff trained	Lab Focal Persons	NACP, GPRTU, PROTIA, CDC, APHL					X	

5.6.4	Train (retrain) 360 ART site staff on sample collection, processing, storage and packaging. (3 staff x 120 sites)	4 x 1 week training completed for staff of ART sites at ER and WR	Number of staff trained	Lab Focal Persons	NACP, CDC, APHL										x	x		
5.6.5	Training (retraining) of 16 VL testing site staff on sample reception, unpacking, safety, documentation and sample processing (4 staff x 4 sites)	4 x 1 week training for staff at VL testing sites completed	Number of staff trained	Lab Focal Persons	NACP, APHL, CDC										x			
5.6.6	Commence sample referral scale up in the 4 regions using selected method(s)	Scale up commence	Number of samples transported from ART sites to testing centres; ART sites sending samples; reports returned to ART sites; sample TAT; missing samples; missing results	Lab Focal Persons	NACP, CDC										x			
5.6.7	Electronic results delivery, Email results for 40 sites (10 sites in each region) and SMS results delivery using SMS printers for 40 sites (10 sites per region). Number of hard copy reports?	Electronic configurations completed. SMS printers installed	Number of results sent via emails Number of results sent via SMS. Number of hard copies of results	Lab Focal Persons, LIS Team	NACP, CDC, CHIM										x	x		

5.6.8	Monitor the sample referral for the 4 regions	Three monitoring visits completed for each region	Number of evaluation visits, evaluation visit reports	Lab Focal Persons	NACP, CDC								X				X	
5.6.9	Data entry, analysis and develop of quarterly reports (per M&E plan)	Final report drafted	Completed final report	Lab Focal Persons	CDC, NACP								X					
5.6.10	Review of reports	Reviews completed	Number of review meetings	Lab Focal Persons	CDC, NACP, TWG, Task Team												X	
OBJECTIVE 6: QUALITY ASSURANCE: To Establish an effective quality assurance program across all VL testing laboratories to assure the quality of patient test results																		
6.1	Strategy 6.1: Perform baseline quality assessment in all the testing labs																	
	ACTIVITY	OUTPUT/ PRODUCT	INDICATOR/ VERIFICATION	RESPONSIBLE	PART-NERS	COST	2017	2018	2019	2017	2018	2019	2017	2018	2019	2017	2018	2019
6.1.1	Assign assessors and assess all labs using CDC VL assessment tool	9 labs assessed	Number of labs assessed	Lab focal person	CDC, APHL									X				
6.2	Strategy 6.2: Implement and monitor IQC and EQA																	
6.2.1	Develop and implement SOPs on IQC and Proficiency Testing in all active VL testing labs	SOPs developed implemented in active VL labs	Number of SOPs in use in all labs	Lab focal person	CDC									X				
6.2.2	Enroll all 9 labs in PT and follow up on poor performance	9 Labs enrolled in PT	Number of labs enrolled in PT	Lab focal person	CDC									X				

6.2.3	Conduct site visits at 9 laboratories twice per annum using CDC VL assessment tool and SOP. Provide supportive site supervision and follow up	Laboratories inspected	Number of laboratories inspected followed up	Lab focal person	CDC									X	X			
6.3 Strategy 6.2: Implement and monitor IQC and EQA																2018	2019	
6.3.1	Develop, disseminate and implement QI SOP in all active VL testing labs	QI SOPS implemented in all active labs	Number of labs with active QI program	Lab focal person, VL lab supervisor	CDC, NACP													
6.3.2	Develop and provide monthly report forms to laboratories	Labs receiving performance feedback	Number of labs receiving reports	Lab focal person, VL lab supervisor	CDC, NACP									X	X		X	
6.3.3	All laboratories to complete monthly QI reports and take corrective action where necessary	Labs have active corrective action activities	Number of labs producing monthly reports	Lab focal person, VL lab supervisor	CDC, NACP									X	X		X	
6.4 Strategy 6.4: Train all staff at all laboratories in Quality Management System																2018	2019	
6.4.1	Conduct TOT training on QMS program for VL testing labs	All VL labs staff have staff trained and competent in QMS	Number of labs that have staff trained in QMS	Lab focal person	CDC, NACP, GF									X				
OBJECTIVE 7: To establish a robust, standardized and fully operational laboratory information system for viral load testing services in 12 laboratories to feed information into DHIMS and e tracker systems by December, 2020.																		
7.1 Strategy 7.1: To interface all PCR Machines with BLIS software and DHIMS-2																2018	2019	
	ACTIVITY	OUTPUT/PRODUCT	INDICATOR/VERIFICATION	RESPONSIBLE	PART-NERS	COST	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4

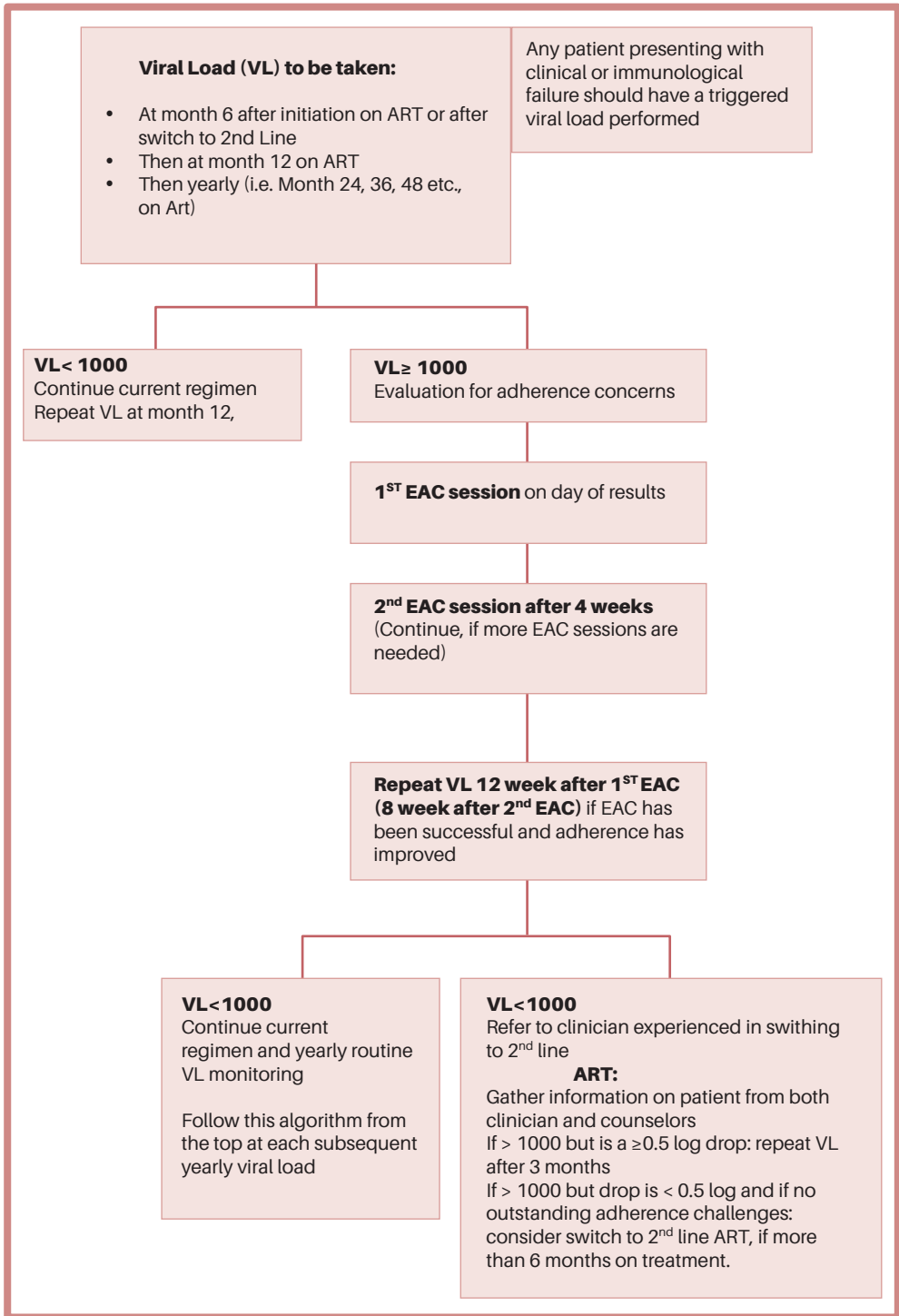
7.1.1	Perform site assessment and support for readiness	12 Site assessed and supported for readiness	12 Site assessed and ready for BLIS deployment	BLIS technical team																			
7.1.2	Procure and install 12 lots of hardware/equipment and software for BLIS implementation at each of the 12 testing sites	BLIS hardware and software installed in 12 sites	Number of sites with BLIS installed	Focal persons (lab STI)	CDC					X													
7.1.3	Undertake a two-day onsite training for 36 site staff of the 12 (3 per site) VL testing sites on the BLIS/DHIMS Interface	Training conducted for 36 staff of 12 VL testing Site	Number of sites reporting in BLIS after the training	NACP/ PPME (CHIM) Staff	PPME-CHIM					X													
7.2		Strategy 7.2: Develop standardized paper based VL forms and registers (Lab request forms, viral load sample referral register, Lab register, test report form)																					
7.2.1	Convene a three-day VL-TWG meeting to design and develop forms, registers and SOPs	3 Forms, 4 registers and their respective job-aids designed and developed	Number of forms and registers developed	Lab Focal Point NACP	CDC (Funding)					X													
7.2.2	Orientate and finalize forms/registers by VL-TWG for 500 laboratory and ART site staff	Orientation of staff and inputs for finalization of documents done	Number of staff give orientation on forms/ registers	Lab Focal Point NACP	CDC (Funding)					X													
7.2.3	Final editing, cleaning, formatting by TWG-VL	Forms, Registers and associated Job-Aids ready for printing	Number of forms and registers and Job-Aids ready for printing	Lab Focal Point NACP/ TWG-VL	CDC/ Global Fund (Funding)					X													

7.2.4	Printing and dissemination of Forms, Registers and associated Job-Aids	3 Forms, 4 registers and their respective job-aids printed	Numbers of each category of Forms, Registers and Job-Aids printed and disseminated	GHS/NACP	CDC/Global Fund (Funding)	X	X								
7.2.5	Conduct TOT on use of VL forms, registers and reports for the regions (3 persons trained per region)	30 regional personnel trained	Number of regions having 3 trained personnel	NACP	CDC	X	X								
OBJECTIVE 5: Implement a sample Referral and results transmission system															
Strategy 8.1: To develop program indicators to monitor scale up program implementation															
8.1	ACTIVITY	OUTPUT/ PRODUCT	INDICATOR	RESPONSIBLE	PARTNERS	COST	2017 Q1	2017 Q2	2017 Q3	2018 Q1	2018 Q2	2018 Q3	2018 Q4	2019 Q1	2019 Q2
8.1.1	Conduct a meeting with service providers and stakeholders/partners to finalize the program indicators	Meeting conducted and viral load program indicator/target documents finalized	number of program and viral load scale up indicators identified to measure set targets	Laboratory focal persons	GHS/NACP, CDC, GF, WHO, UN-AIDS - Funding and Technical Assistance			X							
8.1.2	Incorporate program and lab viral load scale up indicators into DHIMS2	DHIMS2 updated to include program and viral load scale up indicators	number of program and number indicators in DHIMS2	Laboratory focal persons	GHS/NACP, CDC, GF, WHO, UN-AIDS - Funding and Technical Assistance, PPME	\$9,000				X					
8.1.3	Update the existing national HIV M&E Plan to include agreed program and viral load indicators and targets.	National HIV M&E Plan updated to include agreed program viral load indicators and targets	Updated national M&E plan	Number of new program and VL indicators included	GHS/NACP, CDC, GF, WHO, UN-AIDS - Funding and Technical Assistance					X					

								2018	2019		
8.1.4	Conduct quarterly and annual review progress meetings	Quarterly reports written and discussed at quarterly meetings	Number reports and meetings held per year	Laboratory and M&E focal persons	GHS/NACP, CDC, GF, WHO, UN-AIDS - Funding and Technical Assistance			x	x	x	x
8.2	Strategy 8.2 To monitor monthly indicators of viral load testing										
8.2.1	Testing sites to enter viral load data and monthly monitored indicators into BLIS with visibility in DHIMS2	Data entered into BLIS by the testing sites with visibility in DHIMS2 on a monthly basis. To include testing indicators	Monthly BLIS data available by testing site with visibility in DHIMS2. Number of indicators measured	Laboratory staff at BLIS sites	GHS/NACP, CDC, GF, WHO, UNAIDS - Funding and Technical Assistance			x	x	x	x
8.2.2	Extraction of viral load data and indicators from DHIMS2 for analysis and quarterly report writing	Quarterly report compiled and shared	Extracted data available and quarterly report compiled	Laboratory and M&E focal persons	GHS/NACP, CDC, GF, WHO, UNAIDS - Funding and Technical Assistance			x	x	x	x
8.2.3	To share quarterly viral load report with MOH/GHS and stakeholders/partners as part of the program report	Quarterly viral load report shared with MOH/GHS and stakeholders/partners	Number of quarterly viral load report shared	Laboratory and M&E focal persons	GHS/NACP, CDC, GF, WHO, UNAIDS - Funding and Technical Assistance			x	x	x	x

References

1. National HIV Prevalence and AIDS Estimates & Projections Report. 2016.
2. 2016 Annual Report. NACP, GHS
3. Guideline for Antiretroviral Therapy in Ghana. 2016. NACP, GHS
4. WHO 2015. Consolidated Guideline for treatment of Persons Living with HIV
5. Ghana AIDS Commission, 2016. National HIV and AIDS Estimates and Projections Report



Appendix II

Distribution of Gene Xpert Platforms

	DISTRICT	GENE XPERT SITES	TOWNSHIP
UPPER EAST			
1	Kassena Nankana	War Memorial Hospital	Navrongo
2	Builsa North	Sandema Hospital	Sandema
3	Bawku Municipal	Bawku Presby Hospital	Bawku
4	Garu-Tempani	Garu Health Center	Garu
CENTRAL REGION			
1	Abura/Asebu/Kwamankese	Abura Dunkwa Dist Hospital	Abura Dunkwa
2	Mfantsiman Municipal	Saltpond Municipal Hospital	Saltpond
3	Gomoa West	St. Luke Catholic Hospital	Apam
4	Efutu Municipal	Winneba Municipal Hospital	Winneba
5	Awutu Senya East	Kasoa Polyclinic	Kasoa
6	Agona West Municipal	Agona Swedru Municipal Hospital	Swedru
7	Asikuma/Odoben/Brakwa	Our Lady of Grace Hospital	Breman-Asikuma
8	Assin North Municipal	St Francis Xavier Hospital Assin Foso	Assin Fosu
9	Twifo-Ati Mokwa	Twifo Praso Municipal Hospital	Twifo Praso
10	Upper Denkyira East Municipal	Dunkwa on Offin Municipal Hospital	Dunkwa On Offin
WESTERN REGION			
1	Bibiani-Anhweaso-Bekwai	Bibiani Hospital	Bibiani
2	Aowin	Enchi Hospital	Enchi
3	Wassa-Amenfi West	Asankragua Hospital	Asankragua
4	Wassa-Amenfi East	Wassa Akropong Hospital	Wassa Akropong
5	Prestea Huni-Valley	Prestea Hospital	Prestea
6	Tarkwa Nsuaem Municipal	Tarkwa Hospital	Tarkwa
7	Axim Municipal	Axim Hospital	Axim
8	Ellembelle	St Martins de Pores Hospital Eikwe	Eikwe
9	Jomorro	Half Assini Hospital	Half Assini
10	Wiawso	Sefwi Wiawso Hospital	Sefwi Wiawso
11	Juabeso	Juabeso Hospital	Juabeso
GREATER ACCRA			
1	Osu Klottey	Trust Hospital	Osu
2	La Nkwantanan	La General Hospital	La
3	Accra Metro	Achimota Hospital	Achimota
4	Ga West Municipal	Ga West Municipal Hospital	Amasaman
5	Tema Metro	Tema General Hospital	Tema
6	Ga South Municipal	Ga South Municipal Hospital	Weija
7	Dangbe East I	Dangbe East District Hospital	Ada
8	Dangbe West	Dangbe West District Hospital	Dodowa
9	Ashaiman Municipal	Ashaiman Polyclinic	Ashaiman
10	Ledzokoku -krowor	Lekman Hospital	Lekman

EASTERN REGION			
1	West Akim	Asamankese Govt Hospital	Asamankese
2	Upper Manya Krobo	Asesewa Government Hospital	Asesewa
3	Birim Central	Oda Government Hospital	Akim Oda
4	Kwahu Afram Plains North	Presby Hospital, Donkokrom	Donkokrom
5	Denkyembour	St Dominic's Hospital	Akwatia
6	Atiwa	Enyiresi Government Hospital	Enyiresi
7	Kwahu West	Holy Family Hospital	Nkawkaw
8	East Akim	Kibi Government Hospital	Kibi
9	Birim North	New Abirim Hospital	New Abirim
10	Nsawam Adoagyiri	Nsawam Government Hospital	Nsawam
11	Akwapi Nort	Tetteh Quarshie Hospital	Mampong
12	Asuagyaman	VRA Hospital	Akosombo
13	Fanteakwa	Begoro	Begoro
VOLTA REGION			
1	Ketu	Ketu District Hospital, Afiao	Afiao
2	Keta Muncipal	keta Government Hospital	Keta
3	South Tongu	Sogakope Government Hosp	Sogakope
4	Hohoe Municipal	Hohoe Government Hospital	Hohoe
5	Ketu	St. Anthony Catholic Hospital	Dzodze
6	Kpando Municipal	Margaret Macqart Hospital	Kpando
7	Nkwanta South	Nkwanta South District Hospital	Nkwanta
8	Jasikan	Worawora Hospital	Worawora
9	Kadjebi	Mary Theresa Catholic Hospital	Dodi Papase
10	Nkwanta North	Kpassa Health Centre	Kpassa
UPPER WEST REGIION			
1	Nadowli	Nadowli Hospital	Nadowli
2	Lawra	Lawra district Hospital	Lawra
3	Sissala East	Tumu district hospital	Tumu
ASHANTI REGION			
1	Adansi South	New Edubiase Hospital	N. Edubiase
2	Sekyere South	Asamang SDA	Asamang
3	Bekwai Municipal	Bekwai Hospital	Bekwai
4	Asante Akim North	Agogo Presby. Hospital	Agogo
5	Atwima Nwabiagya	Nkawie-Toase	Nkawie
6	Ejisu-Juaben	Juaben Hospital	Juaben
7	Kumasi Metro	Kumasi South Hospital	Kumasi
8	Obuasi	Obuasi Hospital	Obuasi
9	Offinso Municipal	Offinso St. Patrick's Hospital	Offinso
10	Mampong Municipal	Mampong Hospital	Mampong
11	Afigya Kwabre	Ankaase Meth. Hospital	Ankaase

NORTHERN REGION			
1	Yendi Municipal	Yendi Hospital	Yendi
2	East Mamprusi	Baptis Med. Centre	Naleirugu
3	East Gonja	Salaga Hospital	Salaga
4	Bole-Bamboi	Bole Hospital	Bole
5	Saboba	Saboba Hospital	Saboba
6	Tamale Metropolis	Tamale Central Hospital	Tamale
BRONG AHAFO REGION			
1	Asunafo North	Goaso Municipal Hospital	Goaso
2	Kintampo North	Kintampo Municipal Hospital	Kintampo
3	Atebubu-Amantin	Atebubu Hospital	Atebubu
4	Jaman North	Sampa Government Hospital	Sampa
5	Tano South	Bechem Hospital	Bechem
6	Wenchi Municipal	Methodist Hospital -Wenchi	Wenchi
7	Nkoranza South	St Theresa's Hospital -Nkoranza	Nkoranza
8	Pru	Mathias Catholic Hospital	Yeji
9	Berekum Municipal	Holy Family Hospital-Berekum	Berekum
10	Techiman Municipal	Holy Family Hospital, Techiman	Techiman
11	Dormaa Municipal	Presbyterian Hospital	Dormaa Ahenkro
12	Asutifi South	St Elizabeth Hospital	Hwidiem

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